Generic Drugs: Same Medicine, Lower Cost

Perhaps you've had this experience: You go to your local pharmacy to buy medicine. You're inclined to go with the familiar brand name product, the one you know from commercials and other advertising. But the generic version is much less expensive.

"If it's so inexpensive, it must not be as effective or safe," you think.

You would be wrong.

You're not alone. Food and Drug Administration (FDA) pharmacist Brenda Stodart, Pharm.D., who for 14 years has answered questions on FDA's Drug Information line (1-855-543-DRUG) says, "Every day without fail we educate consumers and health care professionals about the safety and efficacy of generic drugs."

So, what are generic drugs and how does FDA ensure they are a safe and effective alternative to name brands?

When a new, FDA-approved drug goes on the market, it may have patent or exclusivity protection that enables the manufacturer to sell the drug exclusively for a period of time. When those expire or no longer serve as a barrier to approval, other companies can make it in generic form. FDA must approve the generic drug before it can be marketed.

An FDA scientist tests how long it takes a tablet to dissolve. To see more photos of the FDA research that helps ensure generic drugs are as good as the name brands, go to: *www.flickr.com/photos/fdaphotos/sets/72157632813235987*

Rigorous Standards

Lawrence Yu, Ph.D., FDA acting deputy director for science in FDA's Office

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of Generic Drugs, explains that for a generic drug to be approved by FDA, its manufacturer must show that it is "equivalent" to the innovator drug (brand name). This means that to gain FDA approval, a generic drug must:

- contain the same active ingredients as the innovator drug. Active ingredients make the drug effective against the disease or condition it is treating.
- come in the same dosage form. If the brand name is a capsule, the generic should be a capsule, too.
- be administered the same way. If the brand name is taken orally, the generic should be taken orally, too.
- be identical in strength
- have the same conditions of use
- be bioequivalent (an equal rate and extent of drug absorbed the bloodstream)
- meet the same standards for identity, strength, purity and quality
- be manufactured under the same standards that FDA requires for the manufacture of innovator products

"Then, and only then, we can assure consumers that the generic will work as well as the name brand," Yu says.

According to Mansoor Khan, R.Ph., Ph.D., the agency's director of the Division of Product Quality Research, the review process includes a review of scientific data on the drug's manufacturing, ingredients and performance.

Sometimes, new complaints or evidence arise indicating that a generic drug may not have the same safety or effectiveness as was previously believed. "If we have reasons to believe a generic drug does not perform the same as a brand name product," Khan says, "we have the ability to perform experiments in the FDA laboratories and take a comprehensive, scientific look at the differences between the products."

This happened with the generic drug Budeprion XL 300 mg, a generic form of Wellbutrin, a drug used to treat depression. FDA's original bioequivalence evaluation had been of a lower dosage (150 mg). After receiving reports of adverse effects from consumers who used Budeprion at the 300 mg dosage level, the FDA conducted another study and determined that Budeprion XL 300 mg was not bioequivalent to the Wellbutrin XL 300 mg.

FDA requested that the manufacturers of Budeprion XL voluntarily withdraw the 300-mg version from the market, which they promptly agreed to do.

While FDA goes to great lengths to ensure that the brand and generic drugs perform equally, in very rare instances, such as Budeprion XL, these efforts do not succeed. BudeprionXL is definitely an outlier, however, Khan says, as there are literally thousands of approved generic products that perform equally without problems or complaints.

The Price is Right

Generic manufacturers are able to sell their products for lower prices because they are not required to develop a new drug from scratch with pre-clinical studies or to repeat the many costly clinical trials of new drugs, Khan says. Generally, they also do not pay for costly advertising, marketing and promotion.

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But not every drug has a comparable generic. To find out if there is a generic equivalent for your brand-name drug, use Drugs@FDA (*http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm*). You can also search for generic equivalents by using FDA's "Electronic Orange Book" (*http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm*). You can also consult the most recent monthly approvals for "First Generics" (*http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/andagenericdrugapprovals/default.htm*).

FDA encourages consumers and health professionals to notify FDA of any adverse side effects found when using drugs and devices the agency regulates, by reporting them online to Medwatch (*https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm*), FDA's safety information and adverse event reporting program, or by telephone at 1-800-FDA-1088.

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